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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/741,730	12/19/2000	Allan F. Willis	KCX-332 (15927)	5590

7590 12/05/2002

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EXAMINER

GHAFOORIAN, ROZ

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 12/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/741,730

Applicant(s)

WILLIS ET AL.

Examiner

Roz Ghafoorian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters; prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 8-20 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 21 and 23-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 December 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Species A in Paper No. 6 is acknowledged. The applicant has further pointed out that claims 16 and 22 do not read on the elected Species A and should not have been examined. Due to the admission of the applicant regarding claims 16 and 22, claims 17-20 will also not be examined since they are depends of claim 16 and hence do not read on the elected Species.

Drawings

2. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

Claim Rejections - 35 USC § 103

3. Claims 1, 3-7, 21, 23, and 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S Patent No.5997503 to Willis et al, and further in view of Patent No.6050934 to Mikhail et al.

Willis teaches a catheter with distally distending balloon. Willis's apparatus is a gastrostomy catheter which comprises of a valve housing defining an opening having a central axis, the opening extending though the valve housing such that the opening forms part of the fluid path though the medical product. It further contains a valve

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member disposed within the opening, the valve member having a single seal interface defined by at least two opposing flexible walls biased towards each other to a sealing position, the valve member having a peripheral portion with the opposing flexible walls extending from the peripheral portion towards the central axis, the opposing flexible walls including ends that contract each other along the single seal interface. Willis, however, does not disclose any information regarding the degree of durometers in the material used to make the valve member. Mikhail discloses a urinary catheter having a palpatable discharge valve with protective shoulders. Mikhail teaches an anti-reflux valve with a valve member made of silicon rubber or other flexible polymeric materials such as Kraton and the like, and preferably having a durometer value of about 12 to about 95 shores. (Col.9, lines 25-30)

Therefore it could have been obvious to one having ordinary skill in the art at the time the invention was made to combine the two teachings, because according to Mikhail by making the valve wall and the valve member form a flexible polymeric material, the valve member can be deformed such that the valve opening can be opened from a closed position when sufficient force is applied to the valve wall to deform the valve member, wherein the valve opening will generally return to the closed position from the open position when the force is no longer applied. (Col.4, lines 55-60)

4. Claims 2, 20, and 24 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,997,503 to Willis et al, and further in view of U.S. Patent Publication No. 004,9501 to Osbourne et al or U.S. Patent No. 5,720,734 to Copenhagen et al.

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Willis teaches a catheter with distally distending balloon. Willis's apparatus is a gastrostomy catheter which comprises of a valve housing defining an opening having a central axis, the opening extending through the valve housing such that the opening forms part of the fluid path through the medical product. It further contains a valve member disposed within the opening, the valve member having a single seal interface defined by at least two opposing flexible walls biased towards each other to a sealing position, the valve member having a peripheral portion with the opposing flexible walls extending from the peripheral portion towards the central axis, the opposing flexible walls including ends that contract each other along the single seal interface. Willis, however, does not disclose any information regarding the thickness of the valve member, however the idea of using a thickness between 0.002 inches to 0.064 inches is well known in the art, the majority of the valve members are within the thickness mentioned above. Copenhaver and Osbourne are just two examples of apparatus with valve members that use thickness between 0.002 inches to 0.064 inches.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have used a thickness of 0.004 inches for the thickness of the valve member; because the valve members are used to be opened and closed depending on the exterior force placed on the valve and it is important to have the valve thick enough so it does not tear and thin enough so it does respond to the external force.

Response to Arguments

5. Applicant's arguments filed 9-24-02 have been fully considered but they are not persuasive:

a. The applicant has argued that Mikhail 934 teaches away from a duckbill valve and therefore the durometers of the valve walls cannot be used in combination with Willis 503. Mikhail does teach away from a uniaxial duckbill valve however the rejection is a 103 combining a duckbill valve that reads on all of the applicant's limitation except for the specific durometers. The combination of the Willis 503 and Mikhail 934 was for the durometers and not the valve. Mikhail teaches that it would be beneficial to have two opposable flexible walls with a durometer ranging from 12-95 on valves because the valve member can be deformed such that the valve opening can be opened from a closed position when sufficient force is applied to the valve wall to deform the valve member, wherein the valve opening will generally return to the closed position from the open position when the force is no longer applied. (Col. 4, lines 55-60). The examiner is not relying on Mikhail teaches for the structure of the duckbill, Mikhail is only used for its reference of the durometers furthermore it is a well known fact that a lower durometer is more flexible than a higher durometer and Mikhail is the motivation that allows for one ordinarily skilled in the art to modify the durometer in the range provided by Mikhail. The benefits of flexible valves are so the patient may open the valve with less force at the time that protection is proved to help minimize inadvertent operation of the valve which is a great advantage for any valve duckbill or not.

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b. Furthermore the applicant has argued that although the range of durometer of applicant's invention is thought in Mikhail 934, Mikhail 934 mostly prefers a durometer of 40 and not less than 20. However, since Mikhail teaches the range in which the applicant has discussed it is a proper to use Mikhail to modify the durometer of the wall valves in the range indicated by Mikhail.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roz Ghafoorian whose telephone number is 703-305-2336. The examiner can normally be reached on 8:30am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

RG
November 26, 2002

A handwritten signature in black ink, consisting of stylized, overlapping loops and a long horizontal stroke extending to the right.A handwritten signature in black ink, appearing to read "Michael Hayes" in a cursive script.
**MICHAEL J. HAYES
PRIMARY EXAMINER**